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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,112	11/18/2003	Claudia Berger	029300.52857US	5872

23911 7590 04/25/2005

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,112	BERGER ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,43-45 and 47* is/are rejected.

7)☒ Claim(s) *30-42,46 and 48-50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/5/04 & 8/27/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/21/2005* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-50 ARE PRESENTED FOR EXAMINATION

Applicants' Information Disclosure Statements filed May 5, 2004 and August 27, 2004 have been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08a, the Examiner has considered the cited references.

Claim Objection

Claims 30-42, 46 and 48-50 are objected to as depending on a rejected base claim (see below), but are otherwise in condition for allowance

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. § 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.,* 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery

of the mechanism underlying a known process does not make it patentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claims 1-5, 7-15, 19-21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldeck et al. (U.S. Patent No. 5,677,297, cited by Applicants).

Waldeck et al. (U.S. Patent No. 5,677,297) teach pharmaceutical compositions comprising a neutral endopeptidase inhibitory compound corresponding to the compound of formula Ia (e.g., present claims 9 and 13; see Waldeck et al. at the abstract, col. 1, line 39 – col. 2, line 55 and Examples I-II at cols. 35-36) which is effective in a method for the treatment of heart failure (col. 14, lines 18-52), which includes cardiac hypertrophy (col. 14, line 48), which comprises the administration of an effective amount of such compositions to a mammal (col. 18, lines 48-64).

The claims subject to the present rejection contain limitations respecting the biochemical characterization of the disease states, e.g., "a disease state in a mammal which can be alleviated by concurrent inhibition of neutral endopeptidase and the metalloprotease IGS5..." (e.g., claim 1), and mechanism of action of the compounds, e.g., "having inhibitory activity a) on neutral endopeptidase and b) on said metalloprotease IGS5" (e.g., claim 1) which are not expressly disclosed by Waldeck et al.

However, such limitations fail to impart patentable moment to the claimed subject matter

because, for the following reasons, they would be inherent in the prior art method.

In particular, in both Waldeck et al. and applicants' claims, the same drug is administered to the same host for the same ultimate therapeutic purpose and thus represent the same patentable method. That applicants may have elucidated a mechanism of action not disclosed by Waldeck et al. is not probative of novelty. It is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. Specifically, discovery of the mechanism underlying a known process does not make it patentable. See *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)).

The remaining claims of Applicants are not subject to the present rejection because the prior art fails to place in the possession of the public the limitations set forth therein. Also, such claims are not subject to a rejection based on obviousness because the conclusion of obviousness would create a circumstance which is merely a possibility, and there the Examiner could not conclude that the presently claimed limitations noted above would be inherent. It has been held that inherency ***must*** be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 212 USPQ 323.

II Claims 1-9 and 16-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldeck et al. (U.S. Patent No. 5,952,327, cited by Applicants).

Waldeck et al. (U.S. Patent No. 5,952,327) teach pharmaceutical compositions comprising a neutral endopeptidase inhibitory compound corresponding to the compound of formula Ib (e.g., present claims 9 and 16; see Waldeck et al. at the abstract, col. 1, line 39 – col. 2, line 47 and Example I at col. 23) which is effective in a method for the treatment of cardiac

insufficiency and high blood pressure (col. 1, line 24), the latter being synonymous with hypertension, (see Stedman's Medical Dictionary at page 745, col. 2 "hypertension", a secondary reference relied on to show the meaning of an expression in the primary reference; see MPEP § 2131.01) which comprises the administration of an effective amount of such compositions to a mammal (col. 12, line 51 – col. 13, line 7).

It is further believed that pulmonary hypertension, heart failure and cardiac hypertrophy would have been placed in the possession of the public from the disclosure of Waldeck et al. '327. In particular, the patentees disclose that the cardiac insufficiency causes a "back-pressure phenomena of the blood...in the pulmonary circulation" (col. 9, lines 8-9) and such is believed to be indicative of a high blood pressure of the pulmonary system. Also, the "cardiac insufficiency" disclosed by Waldeck et al. '327 possesses the same characteristics as described for heart failure, which includes cardiac hypertrophy, in U.S. Patent No. 5,677,297 of Waldeck et al. (Waldeck et al. '297) at col. 14, lines 18-52 and col. 14, line 48 (compare to Waldeck et al. '327 at col. 8, line 63 – col. 9, line 22). Waldeck et al. '297 is here relied on as a secondary reference to show the meaning of an expression in the primary reference; see MPEP § 2131.01.

The claims subject to the present rejection contain limitations respecting the biochemical characterization of the disease states, e.g., "a disease state in a mammal which can be alleviated by concurrent inhibition of neutral endopeptidase and the metalloprotease IGS5..." (e.g., claim 1), and mechanism of action of the compounds, e.g., "having inhibitory activity a) on neutral endopeptidase and b) on said metalloprotease IGS5" (e.g., claim 1) which are not expressly disclosed by Waldeck et al.

However, such limitations fail to impart patentable moment to the claimed subject matter

because, for the following reasons, they would be inherent in the prior art method.

In particular, in both Waldeck et al. and applicants' claims, the same drug is administered to the same host for the same ultimate therapeutic purpose and thus represent the same patentable method. That applicants may have elucidated a mechanism of action not disclosed by Waldeck et al. is not probative of novelty. It is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. Specifically, discovery of the mechanism underlying a known process does not make it patentable. See *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)).

The remaining claims of Applicants are not subject to the present rejection because the prior art fails to place in the possession of the public the limitations set forth therein. Also, such claims are not subject to a rejection based on obviousness because the conclusion of obviousness would create a circumstance which is merely a possibility, and there the Examiner could not conclude that the presently claimed limitations noted above would be inherent. It has been held that inherency ***must*** be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 212 USPQ 323.

III Claims 1-8, 27-29, 43-45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnish et al. (U.S. Patent No. 5,030,654, cited by the Examiner).

Barnish et al. teach pharmaceutical compositions which comprise a neutral endopeptidase inhibitor (see, e.g., the abstract), which may be in the form of biolabile ester (col. 1, line 59 and col. 3, lines 27-30) and, optionally, an ACE inhibitor (col. 11, lines 42-57; compare to present claims 28 and 44; "angiotensin converting enzyme inhibitors") which are useful for the treatment

of such diseases as hypertension, heart failure, renal insufficiency or asthma (col. 1, lines 24-34) which method comprises the administration of an effective amount of such composition to a mammal, such as a human (col. 11, lines 7-41).

Barnish et al. is also believed to have placed the concept of treating pulmonary or renal hypertension (see present claim 6, for example) in the possession of the public given that (i) the patentees teach "various cardiovascular disorders" (col. 1, line 14) and "hypertension" (col. 1, line 26) while Stedman's defines pulmonary hypertension as being secondary to a cardiovascular disease (see page 746, col. 1 "pulmonary h."); and (ii) the patentees teach "renal insufficiency" (col. 1, line 27) and "hypertension" (col. 1, line 26) while Stedman's defines renal hypertension to be secondary to renal disease (col. 1 of page 746). Stedman's is here relied on as a secondary reference to show the meaning of an expression in the primary reference; see MPEP § 2131.01.

The claims subject to the present rejection contain limitations respecting the biochemical characterization of the disease states, e.g., "a disease state in a mammal which can be alleviated by concurrent inhibition of neutral endopeptidase and the metalloprotease IGS5..." (e.g., claim 1), and mechanism of action of the compounds, e.g., "having inhibitory activity a) on neutral endopeptidase and b) on said metalloprotease IGS5" (e.g., claim 1) which are not expressly disclosed by Barnish et al..

However, such limitations fail to impart patentable moment to the claimed subject matter because, for the following reasons, they would be inherent in the prior art method.

In particular, in both Banish et al. and applicants' claims, the same drug is administered to the same host for the same ultimate therapeutic purpose and thus represent the same patentable method. That applicants may have elucidated a mechanism of action not disclosed by the

patentees is not probative of novelty. It is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. Specifically, discovery of the mechanism underlying a known process does not make it patentable. See *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)).

The Examiner has reason to believe that the compounds of Barnish et al. would be the same as functionally described in the present claims because Barnish et al. disclose such compounds as being neutral neuropeptidase inhibitors (see the abstract) while in the present specification at page 19, lines 2-4 of paragraph [0038], Applicants indicate that "compounds which are primarily neutral endopeptidase inhibitors (NEP-inhibitors) are well suited to inhibit also the newly identified IGS5 metalloprotease enzyme.". Thus, the same product in the prior art would appear to be in the present claims. See MPEP § 2112(V). Also, "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).". See MPEP § 2113, last sentence.

The remaining claims of Applicants are not subject to the present rejection because the prior art fails to place in the possession of the public the limitations set forth therein. Also, such claims are not subject to a rejection based on obviousness because the conclusion of obviousness would create a circumstance which is merely a possibility, and there the Examiner could not conclude that the presently claimed limitations noted above would be inherent. It has been held that inherency ***must*** be a necessary result and not merely a possible result. *In re Oelrich* (CCPA 1981) 212 USPQ 323.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 19-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,482,820, cited by Applicants).

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons which establish that the presently claimed subject matter is anticipated by the patented claims.

The claims subject to the present rejection contain limitations respecting the biochemical characterization of the disease states, e.g., "a disease state in a mammal which can be alleviated by concurrent inhibition of neutral endopeptidase and the metalloprotease IGS5..." (e.g., claim 1), and mechanism of action of the compounds, e.g., "having inhibitory activity a) on neutral endopeptidase and b) on said metalloprotease IGS5" (e.g., claim 1) which are not expressly disclosed in the patented claims.

However, such limitations fail to impart patentable moment to the claimed subject matter because, for the following reasons, they would be inherent in the method of the patented claims.

In particular, in both the patented claims and applicants' claims, the same drug is administered to the same host for the same ultimate therapeutic purpose and thus represent the same patentable method. That applicants may have elucidated a mechanism of action not disclosed by the patentees is not probative of novelty. It is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. Specifically, discovery of the mechanism underlying a known process does not make it patentable. See *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)).

Also, the present claims indicate "hypertension" in general (present claims 5, 21, 23 and 24) which would include the "secondary hypertension" of the patented claims. Also, the pulmonary hypertension of present claim 22 is set forth in patented claim 3.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

April 21, 2005